

Sheet 1

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

Complete if Known					
Application Number	10/725,484				
Filing Date	December 3, 2003				
First Named Inventor	Ramon A. Torres				
Group Art Unit	1648				
Examiner Name	Bo Peng				
Attorney Docket Number	TORRES1B				

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
BP	EW	US-6,020,311	02-01-2000	BRAZEAU et al.	
BP	EX	US-5,861,370	01-19-1999	IBEA et al.	
BP	EY	US-5,939,386	08-17-1999	IBEA et al.	
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	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Foreign Patent Number Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (# known)	Publication Date MM-DD-YYYY	of Cited Dogument	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ°				
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Substitute for form 1449A/PTO		Complete if Known		
		Application Number	NOT YET ASSIGNED	
INFORMATION DIS	CLOSURE	Filing Date	ON EVEN DATE HEREWITH	
STATEMENT BY AP	PLICANT	First Named Inventor	Ramon TORRES	
Other marks are		Group Art Unit		
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Sheet 4 of	8	Attorney Docket Number	TORRES=18	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examine Initials*	Cite No.	include name of the author (in CAPITAL LETTERS), title of erticle (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
Se	СО	KOSMISKI et al., "An increase in abdominal girth on protease inhibitor therapy is associated with visceral obesity and metabolic disturbances that closely resemble syndrome", 1st International Workshop on Adverse Drug Reactions and Upodystrophy in HIV, 49-55 (1999)	
	CP	HENRY et al., "Atorvastatin and gemfibrozii for protease-inhibitor-related lipid abnormalities", <u>The Lancet,</u> 352:1031-1035 (1998)	
	CQ	ENGELSON et al., "Altered body fat distribution in HiV infection:regional body composition measurements by whole body MRI and DXA scans", 12th World AIDS Conference Geneva, 471-471 (June 28-July 3 1998)	
	CR	HENRY et al., "Severe premature coronary artery disease with protease inhibitors", The Lancet, 351:1328 (1998)	
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	cw	ABSTRACT - TORRES et al., "The effect of recombinant human growth hormone on protease-inhibitor-associated fat maldistribution syndrome", 675	
	СХ	ABSTRACT - VIARD et al., "Lipodystrophic syndromes in a cohort of HIV-1-infected patients receiving HAART with a protease inhibitor", Abstract No. 026	
	CY	WANKE et al., "Recombinant human growth hormone improves the fat redistribution syndrome (lipodystrophy) in patients with HIV", AIDS, 2099-2103 (1999)	
	CZ	ABSTRACT 031 – RUIZ et al., "A multicentre, randomized, open-label, comparative trial of the clinical, immunological and virological benefit of switching thePI by neviraplne in HAART-experienced patients suffering lipodystrophy", 35	
	DA	ABSTRACT 068 ROZENBAUM et al., "Prospective follow-up of a PI substitution for efavirenz in patients with HIV-related lipodystrophy syndrome" 1555	
88	DB	ABSTRACT 054 – MOLYLE et al., "Changes in visceral adipose tissue and blood lipids in persons reporting fat redistribution syndrome switched from PI therapy to efavirenz" (955)	

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<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. 2 Applicant is to place a check mark here if English tanguage Translation is attached.

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Sheet	5	of	8	Attorney Docket Number	TORRES=18	

			OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
Exam Initials		Cite No.1	include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), data, page(s), volume-issue number(s), publisher, city and/or country where published	T²					
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	1		ABSTRACT 042 - MILANO et al., "Two case reports of unusual lipomatous growths associated with combination antiretroviral therapy"						
			ABSTRACT 038 – MAGGI et al., "Precvocious lesions of the carotid vessels in HiV-1-Infected patients treated with protease inhibitors", 199						
			BSTRACT 018 - MERCIE et al., "Case report of lipidystrophy observations in patients naïve of protease hibitor treatment, angultaine cohort"						
			KRENTZ et al., "Anthropometric, metabolic, and immunological effects of recombinant human growth hormone in AIDS and AIDS-related complex", <u>Journal of Acquired immune Deficiency Syndromes</u> , 6(3)245-251 (1993).						
		DH	ENGELSON et al., "Fat distribution in HIV-infected patients reporting truncal enlargement quantified by whole- body magnetic resonance imagining <sup>13</sup> , <u>Am J Clin Nutr</u> , 69:1162-1169 (1999)						
		DI	BECKER et al., "A nondiabetogenic derivative of human growth hormone", 342:108						
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		DK	CARR et al., "Diagnosis, prediction, and natural course of HIV-1 protease-inhibitor-associated lipodystrophy, hyperlipidaemia, and diabetes mellitus: a cohort study". The Lancet, 353:2093-2099 (1999)						
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		DM	ABSTRACT 006 - ENGELSON et al., "Effect of recombinant human growth hormone in the treatment of visceral fat accumulation in HIV infection: interim analysis", Antiviral Therapy, 4(Supplement 2):19 (1999)						
			HSIUNG et al., "Use of bacterioncin release protein in E. Coli for excretion of human growth hormone into the culture medium", Bio/technology 7:267-271 (1989)						
Si	R		JONES et al., "Crystallization of authentic recombinant human growth hormone", <u>Bio/technology</u> , 5:499-500 (1987)						
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<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Oraw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	STATEMENT BY APPLICANT			First Named Inventor	Ramon TORRES	
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Sheet	6	of	8	Attorney Docket Number	TORRES=1B	

	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published  DP LEWIS et al., "A naturally occurring structural variant of human growth hormone". The Journal of Biological Chemistry, 253:2679-2687 (1978)  DQ LEWIS et al., "Altered protecytic cleavage of human growth hormone as a result of deamidation", The Journal Biological Chemistry, 11645-11650 (1981)  DR ZUREK et al., "Human growth hormone: complementary DNA cloning and expression in bacteria", Science 205:602-607 (1979)  DS ABSTRACT P145 - MAUSS et al., "Successful treatment of Pi-Induced visceral abdominal-fat accumulation with R-human growth hormon"   1/4   5    DT MOCROFT et al., "Changes in AIDS-defining illnesses in a London clinic, 1987-1998", Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 21:401412 (1999)  DU MOORE et al., "Equivalent potency and pharmacokinetics of recombinant human growth hormones with or without an N-terminal methionine", Endocrinology, 122:2920-2926 (1988)  DV WINDISCH et al., "Recombinant human growth hormone for AIDS-associated wasting", The Annats of Pharmacotherapy, 32:437-445 (1998)  DW KOTLER et al., "Studies of body composition and fat distribution in HIV-infected and control subjects", Journal Acquired immune Deficiency Syndromes and Human Retrovirology, 20:228-237 (1999)  DX PINEDA, "Predictable upwelling and the shoreward transport of planktonic larvae by Internal Tidal Bores",	
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